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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,872	09/18/2003	Wayne P. Fitzmaurice	1328-004B	3170
32905	7590	09/08/2005	EXAMINER	
JONDLE & ASSOCIATES P.C. 858 HAPPY CANYON ROAD SUITE 230 CASTLE ROCK, CO 80108			ROBINSON, KEITH O NEAL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,872	FITZMAURICE, WAYNE P.	
	Examiner	Art Unit	
	Keith O. Robinson, Ph.D.	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 September 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 14-18 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 16, 17 and 18 are objected to because of the following informalities:
 - (a) claim 16 should read - - A [The] seed produced from the method of claim 15.--
 - (b) claim 17 should read - - A *Nicotiana* plant, or [its] a [parts] part thereof, produced by growing the seed of claim 16. --
 - (c) claim 18, line 2, the colon in the word "of:" should be deleted.
 - (d) claim 18 should read - - A tissue [Tissue] culture of regenerable cells of the plant, or [its] a [parts] part thereof, of claim 17, wherein the regenerable cells are [selected] produced from a tissue selected from the group consisting of embryos, meristematic cells, pollen, leaves, anthers, roots, root tips, flower, seeds[,] and stems [, protoplasts and calli derived therefrom]. --

Appropriate correction is required.

Specification Objections

2. The use of the trademark GENEWARE (see pages 5, 10 and 11 of the specification) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The 'CROSS REFERENCE' on page 2 of the AMENDMENTS TO THE SPECIFICATION, filed 18 September 2003 is objected to because it does not state that the U.S. Patent Application Serial No. 10/043,198 has been abandoned.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 15-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30-34 of U.S. Patent No. 6,344,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims use the same materials and steps as that of the patent. The 6,344,597 patent teaches a method of producing backcross progeny from interspecific *Nicotiana* hybrids comprising selecting one parent of an interspecific hybrid as a recurrent parent based on a capacity for systemic protein expression from a viral vector and backcrossing said interspecific hybrid to said recurrent parent (see column 9, lines 46-55).

Claim Rejections - 35 USC § 112, first paragraph – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of producing backcross progeny from any interspecific *Nicotiana* hybrids comprising the selection of one parent of any interspecific hybrid as a recurrent parent based on capacity for high level expression of systemic protein from a viral vector and backcrossing said interspecific hybrid to said recurrent parent as well as the seed and parts thereof produced from said method.

The specification fails to provide a written description for the broadly claimed genus of interspecific hybrid *Nicotiana* plants, or seeds thereof, with respect to their genetic, morphological, and/or physiological characteristics; therefore, any tissue culture regenerated from said plants are also not described.

Applicant does not describe what structural features are required for a *Nicotiana* plant to have a capacity for high level expression of systemic protein from a viral vector.

The specification only provides a written description for *N. excelsior* line TW47 and *N. benthamiana* line TW16 (see page 11, lines 3-7).

The specification only provides a written description for the hybrid *Nicotiana excelsiana* 7.b (see pages 12-13, Tables 1-2).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying

characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

7. Claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claim 15 is broadly drawn to a method of producing backcross progeny from any interspecific *Nicotiana* hybrids comprising the selection of one parent of any interspecific hybrid as a recurrent parent based on capacity for high level expression of systemic protein from a viral vector and backcrossing said interspecific hybrid to said recurrent parent. Claims 16-18 are products produced from the claimed method.

The specification only provides guidance for and working examples of a method of producing backcross progeny wherein the parents used were *N. benthamiana* line TW16 and *N. excelsior* line TW47 and wherein the interspecific hybrid produced from this cross was *N. excelsiana* 7.b (see page 11, paragraph 005 and pages 12-14, Tables 1-3). In addition, the specification only provides guidance to the backcrossing of interspecific hybrids to the recurrent parent *N. excelsior* line TW47 (see page 15, paragraph 0056); however, the specification states “[t]he backcross to *N. excelsior* was the only one to germinate” (see page 15, paragraph 0056) which indicates that backcrossing progeny from interspecific *Nicotiana* hybrids may be genotypic specific. The specification also states “[c]ertain crosses may require a multitude of individual pollinations with the hope of obtaining a single seed (see page 9, paragraph 0047). Thus, if the method is not enabled the products produced from the method are not enables.

The use of *Nicotiana* hybrids to produce backcross progeny is unpredictable. The specification fails to teach how many backcross generations are used to produce backcross progeny from interspecific *Nicotiana* hybrids. Ramavarma et al (Tobacco Research 4(1): 29-33, 1978) teach that morphological and chromosomal variability was

observed in the backcross progenies of (*N. benthamiana* x *N. glutinosa*) x *N. tabacum* and that most of the plants were male-sterile. In addition, they teach that further generations (i.e. BC2-BC4) had populations with abnormalities in over 95% of the population (see page 30, first column, first full paragraph and page 32, second column, second full paragraph). Davies (Heredity 32(2): 267-270, 1974) teaches that the production of interspecific hybrid embryos between certain plant species is followed by the selective elimination of the chromosomes of one of the parents (see page 267, first paragraph, lines 1-3). Davies also teaches that this somatic chromosome elimination occurs in the genus *Nicotiana* (see page 267, last five lines of the first paragraph).

The specification teaches “[c]ytological studies of meiosis in some [interspecific] F1 hybrids may show evidence of chromosome irregularities that reflect the chromosomal differences that mark the parents as different species” (see page 1, paragraph 0004). The specification also teaches colchicine may be needed to restore fertility (see page 2, paragraph 0007 and page 7, paragraph 0041), thus one of skill in the art would be required to perform undue trial and error experimentation to determine which interspecific *Nicotiana* hybrids produced from the backcross in the claimed method would require an additional step of adding colchicine to induce fertility. In addition, the specification teaches “[t]he exact backcrossing protocol will depend on the characteristic or trait being altered...methods are simplified when the characteristic being transferred is a dominant allele [although] a recessive allele may also be transferred. In this instance it may be necessary to introduce a test of the progeny to determine the desired characteristic has been successfully transferred” (see page 22,

paragraph 0073). As the desired trait, greater biomass, is not disclosed in the specification as being dominant or recessive, it would require undue trial and error experimentation to use the invention as it is broadly claimed.

Given the breadth of the claims, the lack guidance regarding the broad genus of interspecific *Nicotiana* hybrids, the lack of working examples regarding the broadly claimed method, and the unpredictability of using *Nicotiana* hybrids to produce backcross progeny, it would require undue trial and error experimentation for one of skill in the art to make and use the invention as broadly claimed.

Claim Rejections - 35 USC § 112, second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 14 recites the limitation "of claim 13" in lines 1-2 of said claim. There is insufficient antecedent basis for this limitation in the claim as claim 14 is dependent upon a cancelled claim. This rejection can be obviated by canceling claim 14.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by McCray (Genetics 17: 660-673, 1932).

The claims read on any *Nicotiana* seed or parts thereof produced from backcrossing interspecific *Nicotiana* hybrids with a recurrent parent.

McCray discloses *Nicotiana* seed produced from the backcrossing of interspecific *Nicotiana* hybrids with a recurrent parent (see page 661, third paragraph and page 665, Table 2). See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCray (Genetics 17: 660-673, 1932), in view of Applicant's admission on page 21, paragraph

0071 of the specification. The claim reads on a tissue culture of regenerable cells of the plant or a part thereof of a *Nicotiana* plant produced from backcrossing a *Nicotiana* hybrid with a recurrent *Nicotiana* recurrent parent.

McCray teaches *Nicotiana* seed produced from the backcrossing of interspecific *Nicotiana* hybrids with a recurrent parent (see page 661, third paragraph and page 665, Table 2).

McCray does not teach tissue culturing of regenerable cells of a *Nicotiana* plant.

Applicant teaches, "As is well known in the art, tissue culture of *Nicotiana* can be used for the in vitro regeneration of a *Nicotiana* plant. Tissue culture of various tissues of *Nicotiana* and regeneration of plants therefrom is well known and widely published (see page 21, paragraph 0071).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the method of *Nicotiana* seed produced from the backcrossing of interspecific *Nicotiana* hybrids with a recurrent parent with the well known art technique of tissue culturing *Nicotiana* as admitted by Applicant to produce a tissue culture of regenerable cells of a *Nicotiana*.

One of ordinary skill in the art would have been motivated to make a tissue culture because it would allow the in vitro regeneration of a *Nicotiana* plant.

In addition, one of ordinary skill in the art would have a reasonable expectation of success based on Applicant's admission that tissue culturing of *Nicotiana* is well known in the art.

Conclusion

14. Claim 15 is deemed free of the prior art given the failure of the prior art to teach or suggest a method of producing backcross progeny from interspecific *Nicotiana* hybrids comprising selecting one parent of an interspecific hybrid as a recurrent parent based on capacity for high level expression of systemic protein from a viral vector and backcrossing said interspecific hybrid to the recurrent parent and collecting the resulting seed.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

August 23, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

